

16. 510(k) Safety Summary

DEC 1 8 2001

A. Name of DeviceK013139

Trade Name: Stellartech Coagulation System
Common Name: Electrosurgical Unit and Accessories
Classification Name: Device, Electrosurgical Cutting and Coagulation and Accessories
(21 CFR 878.4400)

B. Predicate Devices

<u>Device</u>	<u>Premarket Notification</u>
Stellartech Radiofrequency Generator Model 1025A-115 and Model 1025A-230	K994173, 01/20/00
ArthroCare Electrosurgery System Generator	K971532, 07/23/99
RadioTherapeutics RF-2000 Radiofrequency Generator	K981672, 07/17/98
ArthroCare Electrosurgery System Probe	K971532, 07/23/99
Ximed Balloon Electrosurgical Probe/Device	K943014, 03/11/96
Boston Scientific Microvasive Gold Probe	K970278, 04/11/97
Bronchus Bronchial Catheter	K980046, 05/01/98
C.R. Bard Eliminator Balloon Dilator	K940965, 05/20/94
Hobbs Medical Dilation Balloon Catheter	K834413, 05/22/84
Boston Scientific Microvasive Rigidflex ABD Achalasia Balloon Dilator	K number unknown

C. Device Description:

The Stellartech Coagulation System consists of the following components.

- Stellartech Coagulation Generator
- Stellartech Coagulation Probe Connection Module
- Stellartech Coagulation Probe
- Optional Stellartech Footswitch.

The proximal end of the Stellartech Coagulation Probe connects to the Stellartech Coagulation Probe Connection Module. The proximal end of the Stellartech Coagulation Probe Connection Module cable connects to the Stellartech Coagulation Generator.

D. Indicated Use

The Stellartech Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

E. Technical characteristics

The technological characteristics of the Stellartech Coagulation System are substantially equivalent to those of the above listed predicate devices.

F. Summary

By virtue of design, principles of operation, materials and intended use, the Stellartech Coagulation System is substantially equivalent to devices currently marketed in the United States.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Mr. James R. Santos
Senior Quality Engineer
Stellartech Research Corporation
1346 Bordeaux Drive
Sunnyvale, California 94089

Re: K013139

Trade/Device Name: Stellartech Coagulation System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 17, 2001
Received: September 19, 2001

Dear Mr. Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

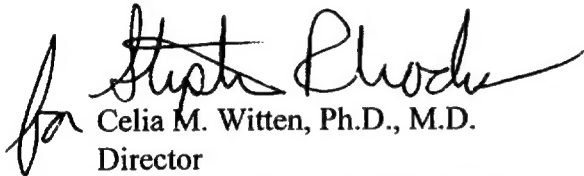
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". To the left of the signature is a small, stylized mark that looks like "for".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K 013139

DEVICE NAME: Stellartech Coagulation System

INDICATIONS FOR USE:

The Stellartech Coagulation System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐

[Signature]
(Division Sign-Off)

Division of General, Restorative
and Neurological Devices